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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,255	02/14/2001	Bruce Marvin Held	N1205-009	1482

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[REDACTED] EXAMINER

SANDALS, WILLIAM O

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1636

DATE MAILED: 02/07/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. <b>09/782,255</b>	Applicant(s) <b>Held et al.</b>
Examiner <b>William Sandals</b>	Art Unit <b>1636</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Feb 14, 2001

2a)  This action is FINAL.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 36-42 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 36-42 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on Feb 14, 2001 is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some\* c) None of:

- 1.  Certified copies of the priority documents have been received.
- 2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- 3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15)  Notice of References Cited (PTO-892)                    18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16)  Notice of Draftsperson's Patent Drawing Review (PTO-948)                    19)  Notice of Informal Patent Application (PTO-152)
- 17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4                    20)  Other: \_\_\_\_\_

*Pd Gy*  
*PT#6*

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## **DETAILED ACTION**

### ***Drawings***

1. This application has been filed with informal drawings which are acceptable for examination purposes only.
2. New formal drawings are required in this application because the 8th edition of MPEP, 608.02(b) no longer permits drawings to be held in abeyance. A copy of PTO form 948, Notice of Draftsperson's Patent Drawing Review is enclosed. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the Patent and Trademark Office no longer prepares new drawings.

### ***Specification***

3. The use of the trademarks TRITON, VORTEX GENIE 2 and LUER-LOK have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. Reference to the old address of the American Type Culture Collection is made in the specification. Correction of the address is required.

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5. The description of Figure 4 begins "figure 4". It should be amended to read "figures 4A and 4B". Correction is required.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 37-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37-42 use the phrase "the promoter". The claims are dependent upon claim 36 which recites a "promoter with known nucleic acid sequences" and a "hybrid promoter". The use of the term "the promoter" in dependent claims 37-42 does not provide a clear distinction between the two antecedent promoters, and as a result, the claims are vague and indefinite.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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9. Claims 36-42 are rejected under 35 U.S.C. 102(a) as being anticipated by Xu et al. (see especially materials and methods and the figures).

Xu et al. taught a method of making a hybrid promoter by combining known sequences from known promoters, thereby producing a new hybrid promoter. The hybrid promoter is tested for activity. The known sequences may have between 60-100% sequence identity to the known promoter sequences. The hybrid promoter may be modified by addition of new sequences, or substitution or deletion of bases in the hybrid promoter and tested for improved promoter activity. At least 15% of the known sequences have been changed in the making of the hybrid promoter, and at least 15% of the new hybrid promoter sequences have been changed to produce an improved hybrid promoter.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 36-42 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Dickson et al. (see especially the materials and methods and the figures) or Shibui et al. (see especially the materials and methods and the figures) .

Each of Dickson et al. or Shibui et al. taught a method of making a hybrid promoter by combining known sequences from known promoters, thereby producing a new hybrid promoter. The hybrid promoter is tested for activity. The known sequences may have between 60-100% sequence identity to the known promoter sequences. The hybrid promoter may be modified by addition of new sequences, or substitution or deletion of bases in the hybrid promoter and tested

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for improved promoter activity. At least 15% of the known sequences have been changed in the making of the hybrid promoter, and at least 15% of the new hybrid promoter sequences have been changed to produce an improved hybrid promoter.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

11. Claims 36-42 are rejected under 35 U.S.C. 102(e) as being anticipated by each of US 5,847,102 (see especially the abstract, summary and figures), US 5,959,094 (see especially the abstract, summary and figures), US 6,162,641 (see especially the abstract, summary and figures), US 6,214,614 (see especially the abstract, summary; the claims and figures), US 6,322,962 (see especially the abstract, summary, columns 32-33 and figures), or US 6,118,049 (see especially the abstract, summary, columns 9-11 and figures).

Each of US 5,847,102, US 5,959,094, US 6,162,641, US 6,214,614, US 6,322,962, or US 6,118,049 taught a method of making a hybrid promoter by combining known sequences from known promoters, thereby producing a new hybrid promoter. The hybrid promoter is tested for activity. The known sequences may have between 60-100% sequence identity to the known promoter sequences. The hybrid promoter may be modified by addition of new sequences, or substitution or deletion of bases in the hybrid promoter and tested for improved promoter activity. At least 15% of the known sequences have been changed in the making of the hybrid

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promoter, and at least 15% of the new hybrid promoter sequences have been changed to produce an improved hybrid promoter.

### ***Conclusion***

12. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Friday from 8:30 AM to 5:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Zeta Adams, whose telephone number is (703) 305-3291.

William Sandals, Ph.D.

Examiner

February 6, 2002

